

ART 31 AMEND

- 1 -

Claims:

1. The use of a buffer based on malic acid for producing a pharmaceutical preparation which can be administered nasally - having substantially improved ciliary tolerability - and is based on an at least partly aqueous solution, emulsion or the like which comprises at least one mucosally absorbable and/or locally acting active pharmaceutical ingredient known per se, at least one preservative formed by benzalkonium chloride alone or together with other preservative substances, at least one buffer which keeps the pH at 4 to 6 or at about 5, and in addition at least one osmotic agent and/or at least one wetting agent and with the proviso that the buffer based on malic acid is employed instead of a buffer previously employed in the pharmaceutical preparation and based on citrate(s), phosphate(s) and/or acetate(s) - partly or completely replacing it (them) - while otherwise retaining the composition, concentration and amount ratios intended for the particular pharmaceutical preparation.
2. The use of a buffer based on malic acid as claimed in claim 1, with the proviso that the malic acid buffer is present therein in a concentration in the range from 1 to 5 mM/l, in each case based on the complete pharmaceutical preparation, for the purpose mentioned in claim 1.
3. The use of a buffer based on malic acid as claimed in claim 1 or 2, with the proviso that the malic acid buffer is formed with sodium as counter ion, for the purpose mentioned in claim 1.
4. The use of a buffer based on malic acid as claimed

in any of claims 1 to 3, with the proviso that the preparation comprises sodium chloride as osmotic agent, for the purpose mentioned in claim 1.

- 5 5. The use of a buffer based on malic acid as claimed
in any of claims 1 to 4, with the proviso that the
preparation comprises
- 10 - at least one allergy remedy such as, for
example, levocabastine, azelastine or cromoglicic acid,
 - at least one sympathomimetic or nasal catarrh
remedy such as, for example, xylometazoline,
15 tetrazoline, indanazoline, phenylephrine,
naphazoline, tramazoline, oxymetazoline,
 - at least one corticoid such as, for example,
20 beclometasone or triamcinolone, and/or
 - at least one peptide or hormone such as, for
example, calcitonin, desmopressin, gonadorelin,
 buserelin, nafarelin or oxytocin,
 - 20 as active ingredient(s), for the purpose mentioned
in claim 1.
6. The use of a buffer based on malic acid in an at
least partly aqueous solution, emulsion or the
25 like which comprises at least one mucosally
absorbable and/or locally acting active
pharmaceutical ingredient known per se, at least
one preservative formed by benzalkonium chloride
alone or together with other preservative
30 substances, at least one buffer which keeps the pH
at 4 to 6 or at about 5, and in addition
preferably at least one osmotic agent and/or at
least one wetting agent and which forms the basis
for a pharmaceutical preparation which can be
35 administered nasally as replacement for the
buffers present in previously known solutions,
emulsions or the like intended for such
preparations and based on citrate(s), phosphate(s)

and/or acetate(s) for the purpose of preparing such a pharmaceutical preparation which can be administered nasally and has a substantially improved ciliary tolerability.

5

7. The use of a malic acid buffer with the proviso or with the provisos

- that it is formed with sodium as counter ion and/or

10

- that it is employed in a concentration in the range from 1 to 5 mM/l, based on the total amount of the pharmaceutical preparation, and/or

- that it is employed together with sodium chloride as osmotic agent, for the purpose indicated in claim 6.

15

8. The use of a malic acid buffer with the proviso that it is employed together with

- at least one allergy remedy such as, for example, levocabastine, azelastine or cromoglicic acid,

20

- at least one sympathomimetic or nasal catarrh remedy such as, for example, xylometazoline, tetrazoline, indanazoline, phenylephrine, naphazoline, tramazoline, oxymetazoline,

25

- at least one corticoid such as, for example, beclometasone or triamcinolone, and/or

- at least one peptide or hormone such as, for example, calcitonin, desmopressin, gonadorelin, buserelin, nafarelin or oxytocin,

30

for the purpose indicated in claim 6, where appropriate taking account of at least one of the provisos of claim 7.

35

9. A process for producing a pharmaceutical preparation which can be administered nasally and is based on an at least partly aqueous solution, emulsion or the like which comprises at least one

5 mucosally absorbable and/or locally acting active
pharmaceutical ingredient known per se, at least
one preservative formed by benzalkonium chloride
alone or together with other preservative
substances, at least one buffer which keeps the pH
at 4 to 6 or at about 5, and in addition at least
one osmotic agent and/or at least one wetting
agent for the use as claimed in any of claims 1 to
8, characterized in that to obtain such a
10 preparation with substantially improved ciliary
tolerability

- a buffer based on malic acid is employed in the
preparation of the solution, emulsion or the
like underlying the preparation, a buffer based
15 on malic acid is present instead of a buffer
which has been employed to date in the
preparation and is based on citrate(s),
phosphate(s) and/or acetate(s) - partly or
completely replacing it (them) - while retaining
20 the composition, concentration and amount
ratios, intended in each case for the
pharmaceutical preparation, of active
ingredient(s), preservative(s), in particular
benzalkonium chloride, and osmotic agent(s) and
25 wetting agent(s).

10. The process as claimed in claim 9, characterized
in that
- a malic acid buffer which is formed with sodium
30 as counter ion is employed, and/or
- the malic acid buffer is employed in a
concentration in the range from 1 to 5 mM/l, in
each case based on the complete pharmaceutical
preparation, and/or
35 - sodium chloride is employed as osmotic agent.

11. The process as claimed in claim 9 or 10, charac-
terized in that the pharmaceutical preparation is

produced with the use of

- at least one allergy remedy such as, for example, levocabastine, azelastine or cromoglicic acid,
- 5 - at least one sympathomimetic or nasal catarrh remedy such as, for example, xylometazoline, tetrazoline, indanazoline, phenylephrine, naphazoline, tramazoline or oxymetazoline,
- at least one corticoid such as, for example, beclometasone or triamcinolone, and/or
- 10 - at least one peptide or hormone such as, for example, calcitonin, desmopressin, as active ingredient(s).

- 15 12. A pharmaceutical preparation which can be administered nasally and is based on an aqueous solution, emulsion or the like which comprises at least one mucosally absorbable and/or locally acting active pharmaceutical ingredient known
- 20 per se, at least one preservative formed by benzalkonium chloride alone or together with other preservative substances, at least one buffer which keeps the pH at 4 to 6 or at about 5, and in addition at least one osmotic agent and/or at
- 25 least one wetting agent and which is characterized in that the preparation has a substantially improved ciliary tolerability owing to the fact that in the solution, emulsion or the like, or in the one underlying it, a buffer based on malic
- 30 acid is present instead of a buffer which has been employed to date in the pharmaceutical preparation and is based on citrate(s), phosphate(s) and/or acetate(s) - partly or completely replacing it (them) - while retaining the composition,
- 35 concentration and amount ratios, intended in each case for the pharmaceutical preparation, of active ingredient(s), preservative(s), osmotic agent(s) and wetting agent(s).

13. The preparation as claimed in claim 12, characterized in that the malic acid buffer is present therein in a concentration in the range from 1 to 5 mM/l, in each case based on the complete pharmaceutical preparation.
14. The preparation as claimed in claim 12 or 13, characterized in that the malic acid buffer is formed with sodium as counter ion.
15. The preparation as claimed in any of claims 12 to 14, characterized in that it comprises sodium chloride as osmotic agent.
16. The preparation as claimed in any of claims 12 to 15, characterized in that it comprises
- at least one allergy remedy such as, for example, levocabastine, azelastine or cromoglicic acid,
 - at least one sympathomimetic or nasal catarrh remedy such as, for example, xylometazoline, tetrazoline, indanazoline, phenylephrine, naphazoline, tramazoline, oxymetazoline,
 - at least one corticoid such as, for example, beclometasone, or triamcinolone, and/or
 - at least one peptide or hormone such as, for example, calcitonin, desmopressin, gonadorelin, buserelin, nafarelin or oxytocin,
- as active ingredient(s).